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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,775	10/03/2005	Michelle M. Hanna	2072.0010009/MAC/SJE	1684

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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10/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,775	Applicant(s) HANNA, MICHELLE M.	
	Examiner Cynthia B. Wilder, Ph.D.	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 16-20 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group IV, claim 21 in the reply filed on 8/3/2007 is acknowledged. Accordingly, the claims 1-11 and 16-20, 22-24 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 21 is vague and confusing because there is no clear nexus between the preamble and method steps. The preamble recites a method for detecting DNA or RNA in a test sample, but the method steps and final step recites "synthesizing multiple reiterative oligonucleotide transcripts" and "detecting or quantifying reiteratively synthesized oligonucleotide. Thus, it cannot be determine if the goal of the preamble is achieved, and if so, in what step. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion (see *ex parte Erlich*, 3 UsPQ2d1011, p.1011 (Bd. Pat, Applicant. Int.1986). Clarification is required as to Applicant's intent.

(b) Claim 21 is indefinite at the abbreviation "APC" because abbreviations often have more than one meaning in the art. It is suggested amending the claim such that it is clear what the abbreviation represent.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Spangler et al (PNAS, Vol. 987, no. 10, pages 5544-5549, May 2001). Regarding claim 21, Spangler et al teach a method comprising hybridizing a single stranded target polynucleotide with an artificial promoter cassette, incubating said target polynucleotide with an RNA polymerase, an initiator and a terminator; synthesizing an oligonucleotide transcript that is complementary to the initiation start site of the artificial promoter and synthesizing multiple reiterative oligonucleotide transcripts and detecting the reiteratively synthesized oligonucleotide transcripts by incorporating a nucleotide analog into the initiator (see page 5545 to 5546, section entitled "Results"). Therefore, Spangler et al meet the limitation of the claim as currently written.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daube et al (Science, 1992, vol. 258, pages 1320-1324, citation made of record on IDS) in view of Sasaki et al (PNAS, March 1998, vol. 95, pages 3455-3466, citation made of record on IDS). Regarding claim 21, Daube et al disclose a method of detecting an oligonucleotide synthesized from a target sequence (see figure 1, "template"), the method comprising: a) hybridizing a primer with single-stranded target sequence (an RNA primer, see page 1320, 3rd column, 2nd paragraph); extending said primer with a polymerase and nucleotides (1321, 1st column, bottom paragraph in the phrase, "[e]ither *E.coli* RNA polymerase or the holoenzyme was added to the construct with all four NTPs..."), such that said polymerase synthesizes multiple template copies (page 1321, 1st column, bottom paragraph, in the phrase, "[t]he products of the transcription reaction....", see also page 1321, 2nd column to 3rd column); and detecting the

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synthesized multiple templates (page 1321, 1st column). The reiterative synthesis is an abortive RNA transcription using an abortive promoter cassette (page 1320, 3rd column to page 1321 and Figure 1).

Daube et al do not expressly teach wherein a terminator is incorporated into the method.

Sasaki et al teach a well-known method of employing chain terminating nucleotides (page 3457, 1st column, bottom paragraph). Therefore, one of ordinary skill in the art would have been reasonably motivated to employ a more environmentally safer alternative, such as fluorescently labeled nucleotide chain terminators, so as to aid in the detection of the terminated transcripts, for the well known and established benefits of using fluorescently labeled nucleotide chain terminators, such as higher sensitivity, and environmentally safer products. One of ordinary skill in the art would have had a clear expectation of success at the combination since the use of chain terminating, fluorescently labeled nucleotides are commonly employed in nucleic acid sequencing reactions which require the transcription to be terminated at the site of its incorporation.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b)

Claim 21 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 15 of copending Application No. 10/607136. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to step of detecting multiple reiterative oligonucleotide transcripts and detecting or quantifying said reiteratively synthesized oligonucleotide transcript. The claims only differ in that that the claims 13 and 15 of copending application 10/607136 is broader in scope than the claim 21 of the instant invention. Thus, the claim 21 of the instant invention falls entirely within the scope of the claims 13 and 15 of copending application 10/607136. As the court stated

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in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application-- "containing a broader claim, more generic in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generic application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

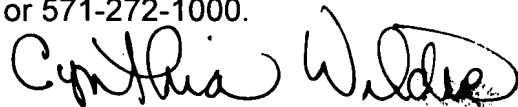
Conclusion

10. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Cynthia B. Wilder". The signature is fluid and cursive, with the first name "Cynthia" being more prominent than the last name "Wilder".

Cynthia B. Wilder, Ph.D.
Patent Examiner
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10/9/2007